

SAMSUNG ELECTRONICS Co., Ltd.

SAMSUNG

510(k) Premarket Notification - Traditional

JUN 20 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted accordance with requirements of 21 CFR 807.92

1. Date: June 6, 2013

2. Submitter

- A. Company Name: SAMSUNG ELECTRONICS Co., Ltd.
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3. Primary Contact Person

- A. Name: Charlie Mack
- B. Title: President of International Regulatory Consultants
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- E. E-Mail: charliemack@irc-us.com

4. Secondary Contact Person

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- B. Title: Regulatory Affairs Manager
- C. Phone Number: +82-31-200-3356
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5. Device

- A. Trade Name: XGEO GU60A
- B. Common Name: Digital Diagnostic X-ray System
- C. Regulation: 21 CFR 892.1680
- D. Classification Name: System, X-ray, Stationary
- E. Product Code: KPR

6. Device Description

The XGEO GU60A digital X-ray imaging system is to be used to take and store image for

diagnosis of patients. It consists of the High voltage generator (HVG), U-arm positioner, Detector, X-ray tube, Collimator and etc.

7. Intended Use

The XGEO GU60A Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.

8. Comparison with predicate device :

Samsung Electronics Co., Ltd., believes that the XGEO GU60A is substantially equivalent to the Revolution XR/d of General Electric Company.

Comparison with the predicate device made through the system component items such as detector, generator etc., has been proven to be similar in many ways, but differences in the seven items were found. Specifically, even if the differences of the capacity and size of High Voltage Generator, Ceiling Suspension, Wall stand and Patient table exists, these are considered minor impact on the safety and performance. Also, Collimator, Detector, and Image Process Function in terms of the design and the technology characteristic have differences in the following characteristics:

- 1) Configuration : PD and the proposed device have different configurations. PD is a ceiling type and the proposed device is a U-arm type. But it has no effect on safety.
- 2) Auto Positioning : The proposed device provides the auto positioning function. But it has no effect on safety.
- 3) High Voltage Generator : The specifications of high voltage generators are different. But it has no effect on safety. The proposed device has the lower output rating and wider time range which makes the mAs range of both devices similar.
- 4) Blade moving method: Motorized method for adjusting a collimator radiation field is only available. It just concerns on the method for control a radiation field and has not effect on safety.
- 5) Number of pixels : Number of pixels is different. A detector with a large number of pixels can cover a wider area of body. It has no effect on safety.
- 6) Pixel pitch : Pixel pitch, a measurement that indicates the distance between pixels and determines an image resolution, is different. It affects the image quality but it has

not effect on safety.

7) High contrast limiting resolution : High contrast limiting resolution is different due to the difference of the pixel pitch. The resolution is higher as the value of the pixel pitch is lower. It affects the image quality but it has no effect on safety.

8) DQE : The value of DQE is different. The detector type with CSI phosphor has higher DQE value. It affects the image quality but it has no effect on safety.

9) MTF : The value of MTF is different. The detector type with CSI phosphor has higher MTF value. It affects the image quality but it has no effect on safety.

10) Robust FPD : PD and proposed device have "Flat Panel Detector". And detector in proposed device has been passed reliability test (include drop test) so it is named "Robust FPD".

11) Adaptive Local Contrast Stretching : PD and proposed device have "Contrast enhancement image processing algorithm". And "Algorithm" in proposed device name is "ALCOS"

12) Remote Access : PD and proposed device have "Remote Access" function for Remote management system

13) Collision Avoidance System : PD and the proposed device have a function that prevents collisions with foreign objects, but detection sensors are different.

14) Micro Processor Controlled High Frequency Switching : PD and the proposed device have HVGs that include a microprocessor-based control system. Also, the control system uses a high frequency switching method to provide the required voltage and current outputs.

15) Full-Auto (Adaptive) mA Calibration : PD and the proposed device have the auto mA calibration function that can compensate for effects like filament aging. "Adaptive mA Calibration" is also used for the same function.

However, these differences do not have an effect on safety and effectiveness compared with the predicate device, Revolution XR/d of General Electric Company.

In summary, the XGEO GU60A does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

In conclusion, the XGEO GU60A is substantially equivalent to Revolution XR/d of General Electric Company.

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9. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32, IEC 60601-2-54, 21CFR1020.30 and 21CFR1020.31 were performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001).

And Non-clinical testing and Clinical Testing were conducted in accordance with Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" (issued August 6, 1999). All test results were satisfied.

10. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Samsung Electronics Co., Ltd. concludes that The XGEO GU60A is safe and effective and substantially equivalent to predicate devices as described herein.

11. Samsung Electronics Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2013

SAMSUNG ELECTRONICS Co., Ltd.
% Mr. Charlie Mack
Principle Engineer
International Regulatory Consultants (IRC)
77325 JOYCE WAY
ECHO OR 97826

Re: K123106

Trade/Device Name: XGEO GU60A Digital Diagnostic X-ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: May 21, 2013
Received: May 29, 2013

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123106

Device Name: Digital Diagnostic X-ray System

Indications for Use:

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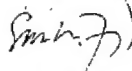
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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